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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,836	08/03/2001	Andrew Bett	20377YP	7869
210	7590	01/14/2004	EXAMINER	
MERCK AND CO INC P O BOX 2000 RAHWAY, NJ 070650907			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	12

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/890,836

**Applicant(s)**

BETT ET AL.

**Examiner**

Myron G. Hill

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8/11/03.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1- 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1- 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

This action is in response to amendment filed 17 August 2003.

### ***Sequence Requirements***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant has placed the sequences in the claims in compliance. Objection withdrawn.

### ***Information Disclosure Statement***

Applicant acknowledges that the application did not contain an IDS previously.

Applicant has submitted an IDS (paper #10, filed 8/11/03) and an initialed and signed copy is included with this action.

### ***Claim Objections Maintained***

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Claims 10- 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims 10- 13 depend on a claim that is a nucleic acid.

The claims have been amended to recite a nucleic acid comprising a helper virus.

This is not sufficient to overcome the objection. A helper virus can comprise a nucleic acid but not the other way around.

***Rejections Withdrawn***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 14 was rejected under 35 U.S.C. 102(e) as being anticipated by Graham (US 5,919,676).

Applicant has amended the claim to be dependent ultimately from claim 1.

The art no longer applies. Rejection withdrawn.

Claim 15 was rejected under 35 U.S.C. 103(a) as being unpatentable over Graham (US 5,919,676).

Applicant has amended the claim to be dependent ultimately from claim 1.

The art no longer applies. Rejection withdrawn.

Claims 6, 8, 9, and 12- 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hardy.

Applicant's arguments that Hardy does not teach the limitations are persuasive and the rejection is withdrawn.

***Rejections Maintained***

***Claim Rejections - 35 USC § 112***

Claims 1- 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what metes and bounds of "low homology" is and it is not clear what the function or property of the packaging signal is relative to the wild-type. It is not clear how a nucleic acid can be a helper virus in claim 10. Claim 7 is not definite in what "2-3 times less efficient" relates to because Hardy (as discussed below) teaches the same construct in different host cells has different packaging efficiencies (page 39, lines 18- 20). In claim 8 it is not clear what is the consensus sequence. Is it the consensus the "A" element or is it the sequence in the nucleic acid molecule?

Applicant argues that the terms are defined in the specification and that the A element is defined in Schmid and Hearing (1997, J of Virology, of record) and is known in the art.

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Applicant's arguments have been fully considered and found persuasive in part.

The meaning of "A element" and helper virus are clear.

The other terms are not clear. Page 4 defines "low homology" but the basis appears to be "100% identity" with a region and the definition is not clear because there is no relative basis for size or region that is compared. Does the packaging signal contain deletions or substitutions? It is not clear what the size is if it is just the 23 bps or comprises the 23 bps. The structure of the defined region is not clear.

The term "less efficient" is defined in terms of cells expressing recombinase versus cells that do not express recombinase and the titer of virus that can be achieved in those cells without recombinase. It is clear from the definition and the example cited by the Examiner that the term is relative and needs a specific basis for the definition. The rejection of the above two terms is maintained.

### ***Claim Rejections - 35 USC § 102***

Claims 1- 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardy (WO97/32481).

Applicant argues that the term "low homology" is defined and that Hardy does not meet this. Applicant also describes the modifications as within the variable portions of the "A element" (8 bases in the middle) and the A elements and variable regions have been switched.

The arguments have been fully considered and not found persuasive.

As discussed in the 35 U.S.C. 112, second paragraph, above, the definition is not clear and Hardy for reasons of record in the previous Office Action anticipate the claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the variable portions of the A elements and switching of A elements) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is also noted that these features are not in the definition on page 4 for "low homology".

Claims 6, 8, and 9- 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardy.

Applicant argues that the claims depend from a claim containing a novel feature and that Hardy does not teach the novel element of claim 1 but does teach features of the dependent claims.

Applicant's arguments have been fully considered and not found persuasive.

Hardy as applied to the novel feature of claim 1 is discussed above and the rejection is maintained for reasons set out in the previous rejection.

### ***Conclusion***

No claim is allowed.

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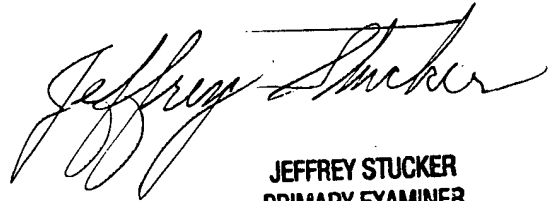
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Myron G. Hill  
Patent Examiner  
January 11, 2004



JEFFREY STUCKER  
PRIMARY EXAMINER